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REMARKS

The examiner is thanked for the very thorough and professional office action and for the detailed response to applicants' arguments. Pursuant to that office action, Claims 10 and 11 have been cancelled and the subject matter of these claims incorporated into Claim 1. Also, the term "comprising" in Claim 1 has been changed to "consisting essentially of". Additionally, the dependency of Claim 12 has been changed to Claim 1. This amendment is believed to more definitely set forth the invention and obviate the rejections. Claim 1, the only independent claim pending in this case, is now restricted to an adhesive gel composition for iontophoretic formulations containing water-soluble steroid hormone(s) which form anions in the adhesive gel composition of the iontophoretic formulations and which can be delivered from the cathode side of the iontophoretic formulation(s). Since the amendment of claim 1 merely incorporates the subject matter of Claims 10 and 11, it is believed that the present amendment does not introduce new matter. It is therefore believed that the present amendment does not raise any new issues requiring any further search. Claims 1, 4, 5, 7, 9, and 12-15 remain the only pending claims in this application,

Reconsideration is respectfully requested of the rejection of Claims 1, 4-5, 7, 9-10, and 13 under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP'985).

As indicated above, all of the claims remaining in the application are restricted to water-soluble steroid hormone(s) which form anions in the adhesive gel composition of the iontophoretic formulation(s) and which can be delivered from the cathode side of the iontophoretic formulation(s). Importantly, it is respectfully submitted that these water-soluble steroid hormone(s) now called for in all of the claims do not include lidocaine and epinephrine which are described in the cited reference (EP'985). It is therefore clear that the claims

remaining in the application do not cover the drugs disclosed in EP'985. It is equally clear that EP'985 does not anticipate or render unpatentably obvious the subject matter now called for in the claims herein.

Moreover, the acidic polymer employed in EP'985 is not a neutral acid but instead is an acidic polymer such as polyacrylic acid as described in EP'985. The polyacrylic acid is not used as a gelatinizing agent singly in hydro gel compositions. In order to gelatinize polyacrylic acid, it must be used in the composition in very high concentrations. But, usually, a relatively low concentration of polyacrylic acid is used with pH controlling agent(s) such as sodium hydroxide and triethanol amine and the like so as to provide a gelatinizing effect.

However, in the EP'985 reference the use of such an alkali component is neither taught nor disclosed. The reason why such an alkali component is not used is that if such an alkali component is incorporated in the composition of the cited reference (EP'985), the alkali component will compete with the basic drug so as to decrease the ion transportation efficiency of the drug. In the cited reference of EP'985, the basic drug such as lidocaine and epinephrine appears to act as a pH controlling agent to form a gel.

In contrast, in the present invention, in order to obtain a gel the same as in the EP'985 reference, an acidic polymer has to be present in a very high concentration. However, if an acidic polymer is present in such a very high concentration, the blood level of drug cannot be obtained as illustrated in the specification on page 49, in Table 12.

In addition, if the basic drug in the EP'985 reference is substituted by the nonionic water-soluble steroid hormone(s) in the present invention, the gelatinization of the composition is not possible. Therefore, Claim 1 has been amended to change the term "comprising" to "consisting essentially of" to exclude ingredients which would affect the basic and novel characteristics of the product. For example, the term "consisting essentially of" is believed to exclude drugs such

as lidocaine and epinephrine which would change the basic and novel characteristics of the product. It is also intended to exclude the use of an acidic polymer in very high concentrations which would prevent the presence of the drug in the desired concentrations. See *In re Garnero*, 412 F2d 276, 162 USPQ 221 (CCPA 1969).

For these reasons, the composition now called for in the claims herein is not patentably obvious in view of the EP'985 reference. Consequently, the examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1, 4-5, 7, and 9-14 under 35 U.S.C. 103(a) as being unpatentable over EP'985 in view of Nowicki.

The deficiencies of the examiner's primary reference of EP'985 reference are discussed above.

In order to cure the deficiencies of the primary reference of EP'985, the examiner then relies upon a secondary reference of Nowicki which discloses the administration of corticosteroids such as dexamethasone sodium phosphate. It is respectfully submitted that Nowicki nowhere discloses an adhesive gel composition for iontophoretic formulations as now called for in the claims herein, nor does Nowicki disclose a water-soluble steroid (s) which form anions in the adhesive gel composition of iontophoretic formulations.

In view of the deficiencies of Nowicki discussed above and the amendments to claim 1 herein, it is respectfully urged that the claims now in the case patentably distinguish from the examiner's combination of references, taken individually or in combination. For this reason, the examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

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Reconsideration is respectfully requested of the rejection of claims 1, 4-5, 7, 9-10 and 13-14 under 35 U.S.C. 103(a) as being unpatentable over EP'985 in view of the secondary reference of Green, et al., U.S.Patent 5,682,726.

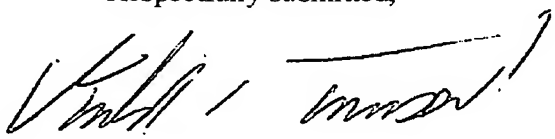
The deficiencies of the examiner's primary reference of EP'985 are discussed above.

In order to cure the deficiencies of the primary reference of EP'985, the examiner relies upon the secondary reference of Green, et al., ('726). It is respectfully urged that the examiner's reliance upon the '726 reference is misplaced because this secondary reference of Green, et al. does not perform the same function as in the present application. In particular, the '726 reference of Green, et al. discloses a method for forming an iontophoretic patch involving forming a laminate having a chamber between a first and second laminate, and inserting an inert gas into said chamber.

In contrast, in the present invention, oxygen dissolved in the gel is positively removed by replacement with nitrogen and/or vacuum kneading at the time ingredients are added and kneaded. There is no disclosure of injecting an inert gas into the patch. Instead, the oxygen is removed from the gel as it is being mixed. It is respectfully urged that these two methods are entirely patentably distinct; consequently, the examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,



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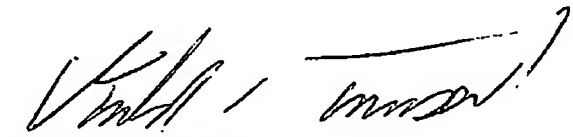

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